

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION**

)
) **MDL No. 1456**
) **Master File No. 01-CV-12257-PBS**
) **Subcategory Case. No. 06-11337**
)

THIS DOCUMENT RELATES TO:

) **Hon. Patti B. Saris**
)

*United States of America ex rel. Ven-A-Care of the
Florida Keys, Inc., et al. v. Dey, Inc., et al.,*
Civil Action No. 05-11084-PBS

) **Magistrate Judge**
) **Marianne B. Bowler**
)
)

**DEFENDANTS DEY, INC., DEY, L.P., AND DEY L.P., INC.'S
MOTION FOR LEAVE TO FILE A REPLY MEMORANDUM
OF LAW IN FURTHER SUPPORT OF THEIR MOTION TO
COMPEL LUIS COBO AND VEN-A-CARE OF THE FLORIDA
KEYS, INC. TO PRODUCE DOCUMENTS**

Pursuant to Rule 7.1(b)(3) of the Local Rules for the District of Massachusetts, Defendants Dey, Inc., Dey, L.P., and Dey L.P., Inc. (collectively, "Dey"), seek leave of Court to file a Reply Memorandum of Law in Further Support of Their Motion to Compel Luis Cobo and Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") to Produce Documents concerning Cobo Pharmacy responsive to Dey's Subpoena *Duces Tecum* to Luis Cobo and Dey's First Set of Requests for Production of Documents and Tangible Things to Ven-A-Care.

Ven-A-Care and Luis Cobo have consented to Dey's request to file a reply memorandum of law.

Defendants Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s proposed Reply Memorandum of Law in Further Support of their Motion to Compel Luis Cobo and Ven-A-Care of the Florida Keys, Inc. to Produce Documents is annexed hereto as Exhibit 1.

CERTIFICATIONS PURSUANT TO LOCAL RULES 7.1 AND 37.1

I, Clifford Katz, hereby certify that I have conferred with Alison W. Simon, Esq., counsel for Ven-A-Care of the Florida Keys, Inc. and Luis Cobo, on January 26, 2009, January 27, 2009 and January 28, 2009, and certify that Ven-A-Care and Luis Cobo have consented to Dey's request to file a reply memorandum of law.

Dated: January 29, 2009

Respectfully Submitted,

/s/ Clifford Katz

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on January 29, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Clifford Katz

Clifford Katz

EXHIBIT 1

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION**

)
) **MDL No. 1456**
) **Master File No. 01-CV-12257-PBS**
) **Subcategory Case. No. 06-11337**
)

THIS DOCUMENT RELATES TO:

*United States of America ex rel. Ven-A-Care of the
Florida Keys, Inc., et al. v. Dey, Inc., et al.,*
Civil Action No. 05-11084-PBS

) **Hon. Patti B. Saris**
)
) **Magistrate Judge**
) **Marianne B. Bowler**
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)
)

**DEFENDANTS DEY, INC., DEY, L.P., AND DEY L.P., INC.'S REPLY
MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR
MOTION TO COMPEL LUIS COBO AND VEN-A-CARE OF THE
FLORIDA KEYS, INC. TO PRODUCE DOCUMENTS**

INTRODUCTION

Defendants Dey, Inc., Dey, L.P., and Dey L.P., Inc. (collectively, "Dey"), by their attorneys, hereby submit this reply memorandum of law in further support of their motion to compel Luis Cobo ("Cobo") and Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") to produce documents concerning Cobo Pharmacy, which are responsive to Dey's Subpoena *Duces Tecum* (the "Subpoena") to Cobo, and Dey's First Set of Requests for Production of Documents and Tangible Things to Relator Ven-A-Care of the Florida Keys, Inc. ("Document Requests to Ven-A-Care") (the responsive documents are referred to herein as the "Cobo Pharmacy documents").

Ven-A-Care and Cobo argue that they should not be compelled to produce the Cobo Pharmacy documents because Cobo and Cobo Pharmacy are third-parties and the documents are irrelevant and/or duplicative. These arguments are meritless as set forth herein and in Dey's moving Memorandum of Law, filed December 2, 2008 ("Moving Memorandum").

ARGUMENT

I.

**LUIS COBO SHOULD BE COMPELLED TO PRODUCE THE
COBO PHARMACY DOCUMENTS PURSUANT TO THE SUBPOENA**

**A. Luis Cobo and Cobo Pharmacy Are Integrally Involved With Ven-A-Care
and Have Participated in Investigations and Litigations Concerning Dey**

Luis Cobo is not a third party that is a stranger to this litigation. As Ven-A-Care and Cobo concede, Cobo is a principal of both Ven-A-Care and Cobo Pharmacy. *See* Joint Response to Motion to Compel Luis Cobo and Ven-A-Care of the Florida Keys, Inc. to Produce Documents, dated January 9, 2009 (“Ven-A-Care and Cobo’s Resp.”) at pp. 1-2. Plaintiffs’ First Amended Complaint specifically alleges that Cobo is a principal officer and/or director of Relator Ven-A-Care during the relevant time period. *See* First Am. Compl. at ¶ 11. Cobo has been involved in investigations and litigations concerning Dey, since at least as early as 1995.

The following are some examples of Cobo’s involvement:

- On September 14, 1995, Cobo participated in a meeting with representatives of the United States Department of Health and Human Services (“HHS”), the HHS Office of Inspector General, the United States Department of Justice, and the Health Care Financing Administration (“HCFA”), in which representatives of Ven-A-Care presented the alleged fraud scheme allegedly being committed by drug manufacturers. *See* Declaration of Clifford Katz in Further Support of Dey’s Motion to Compel, dated January 29, 2009 (“Katz Reply Decl.”), Ex. A. At this meeting, Ven-A-Care specifically referred to Dey’s drugs. *See id.* at VAC MDL 86175; Katz Reply Decl., Ex. B, 3/4/08 Cobo Tr., at 431:21-437:14; Katz Reply Decl., Ex. C, 12/8/08 Jones Tr., at 835:14-842:6.
- Starting in 1998, Cobo participated in a presentation to the Administrator of HCFA, Nancy-Ann Min DeParle, and presentations to state governments. *See* Katz Reply Decl., Ex. B at 3/4/08 Cobo Tr., at 305:20-313:19.
- On May 16, 2001, a wholesaler, J.J. Balan sent Cobo at Ven-A-Care prices for Dey’s drugs. Ven-A-Care then forwarded these prices to the OIG on the same day. *See* Katz Reply Decl., Ex. D.

Additionally, Cobo used Cobo Pharmacy to collect information relating to Dey, which was then provided to Ven-A-Care, which then disseminated the information to state and federal governments. The following are some examples:

- On July 26, 1997, Zachary Bentley and T. Mark Jones, principals of Ven-A-Care, sent a facsimile to Jerry Wells, the head of the pharmacy program of Florida Medicaid, attaching prices for Dey's albuterol 0.083%. *See* Katz Reply Decl., Ex. E. The facsimile included an invoice from McKesson to **Cobo Pharmacy**. *See id.* at VAC MDL 65910.
- On March 22, 2000, Dey sent a facsimile to Cobo Pharmacy, attaching rebate information. *See* Katz Reply Decl., Ex. F. Cobo Pharmacy forwarded this facsimile to Ven-A-Care as it was later produced from the files of Ven-A-Care during the action, *State of Texas v. Dey, Inc., et al.*, Texas State Court, Travis County, Case No. GV 002327, as evidenced by the R1 Bates prefix. *See* Katz Reply Decl., Ex. C, 12/8/08 Jones Tr., at 851:2-7. This document was also produced by Ven-A-Care in this action and was marked VAC MDL 53665.

In addition to sharing information, Cobo Pharmacy and Ven-A-Care shared employees. Cobo was the "pharmacist in charge" at both Cobo Pharmacy and Ven-A-Care. *See* Declaration of Clifford Katz, dated December 1, 2008 ("Katz Moving Decl."), Ex. C, 7/31/08 Cobo Tr., at 606:7-14, 742:5-11. Ven-A-Care hired pharmacists working for Cobo Pharmacy on a part-time basis as needed when Cobo was not available to work at Ven-A-Care. *See* Katz Reply Decl., Ex. C, 12/8/08 Jones Tr., at 741:17-744:4. Additionally, as Ven-A-Care and Cobo concede, Ven-A-Care purchased drugs from Cobo Pharmacy. *See* Ven-A-Care and Cobo's Resp. at p. 5.

**B. The Cobo Pharmacy Documents Are Relevant
To The Claims And Defenses In This Action**

1. Documents Concerning Luis Cobo's Audit of Cobo Pharmacy Are Relevant

As conceded by Ven-A-Care, Cobo performed an audit of Cobo Pharmacy at the suggestion of Zachary Bentley, another principal of Ven-A-Care. *See* Ven-A-Care and Cobo's Resp. at p. 9. Dey seeks documents concerning this audit. Ven-A-Care and Cobo's argument that Cobo's audit is not relevant because Cobo's actions cannot bind the Government misses the point. The issues of whether Medicaid pharmacy providers, like Cobo Pharmacy, were overpaid, how much they were overpaid, and whether the pharmacies or manufacturers need to pay the money back are factual issues central to this case. The audit documents incontrovertibly relate to all of these issues. In the event plaintiffs' claims survive summary judgment, a jury will need to decide these issues with respect to Cobo Pharmacy, among other pharmacies, because Cobo Pharmacy submitted claims to Florida Medicaid for Dey's drugs and plaintiffs are seeking damages on those very claims.

Even Cobo recognized that the audit may be relevant to this litigation: "I felt -- I felt that if I'm going to be an active participant in this lawsuit, then certainly I had an obligation to try to, you know, rectify anything that I had seen that would -- that has been problematic for the program on a much, much larger scale." *See* Katz Moving Decl., Ex. C, 7/31/08 Cobo Tr., at 794:5-10; *see also id.* at 792:8-794:12. Additionally, Zachary Bentley, another principal of Ven-A-Care, also acknowledged the relevancy of the audit to this litigation:

Q. When you learned this information that led to the conversation with Mr. Cobo, you were pretty upset that this was going on at the Cobo Pharmacy, because it might be inconsistent with what you were alleging; isn't that right?

* * *

A. Was I -- was I mad? Yes.

See Katz Reply Decl., Ex. G, 11/6/08 Bentley Tr., at 795:18-796:6.¹

**2. Documents Concerning Cobo Pharmacy's
Usual and Customary Charges Are Relevant**

Citing to the decision in *Commonwealth of Massachusetts v. Mylan Labs. Inc. et al.*, Civil Action No. 01-11865, at pp. 41-42 (D. Mass. Dec. 23, 2008) (the “*Massachusetts Decision*”), Ven-A-Care and Cobo argue that documents concerning Cobo Pharmacy’s Usual and Customary Charges (*i.e.*, billed amounts) (“U&Cs”) are not relevant because Cobo Pharmacy’s U&Cs are immaterial. The *Massachusetts Decision* does not address the materiality argument Dey makes in this action. The *Massachusetts Decision* concerns an argument based on the assumption that the providers’ U&Cs are false. Here, Dey’s argument does not make that assumption, but rather assumes the U&Cs to be true based on plaintiffs’ failure to allege that the U&Cs are false. Dey’s argument is: the only claims submitted for purposes of the False Claims Act are claims certified as true and accurate by pharmacists. If these U&Cs are as certified, then no false claim was submitted. The fact that a true claim may have been reimbursed at a lesser amount based on an alternative reimbursement theory does not alter the claim as presented and certified.

The *Massachusetts Decision*, Ven-A-Care and Cobo also do not address Dey’s argument that, based on the measure of damages applied to claims for fraud and under the False Claims Act, there can be no damages when reimbursement was based on AWP or WAC because the Medicaid program paid less than the U&C, and thus, less than the value of the service. Cobo Pharmacy’s documents concerning how the U&Cs were calculated are needed to demonstrate

¹ Since Ven-A-Care and Cobo claim not to have any documents relating to the audit performed of Cobo Pharmacy by Florida Medicaid, *see* Ven-A-Care and Cobo’s Resp. at p. 5, Dey does not provide further argument as to the discoverability of those documents, but reserves the right to do so if Cobo or Ven-A-Care discover responsive documents in their possession, custody or control.

that the Medicaid program received a discounted market price when it paid on the basis of AWP or WAC.

Zachary Bentley's testimony implies that Cobo Pharmacy's U&Cs may be relevant to any alleged "overpayments" made by Florida Medicaid to Cobo Pharmacy and Cobo Pharmacy's subsequent "repayment." *See* Katz Reply Decl., Ex. G, 11/6/08 Bentley Tr., at 773:10-798:3. Bentley indicates that the U&C charged by Cobo Pharmacy to its customers was a real market price, and if Cobo had reduced its U&C to reduce the amount Florida Medicaid paid Cobo, Cobo would have been "cheating himself." *See id.* at 796:18-798:3. In other words, if a pharmacy charges Medicaid and other customers less than the U&C – its market price – it is cheating itself.

Florida Medicaid has defined the U&C as an amount billed by the pharmacy to a defined group of customers. *See* Moving Mem. at p. 6. Thus, Medicaid could not have been defrauded when it paid on the basis of AWP or WAC because it paid less than the certified U&C, as defined by Florida Medicaid. Requests for documents showing how Cobo Pharmacy calculated its U&Cs are reasonably calculated to lead to the discovery of admissible evidence showing how Florida Medicaid was not defrauded when it paid below the U&C, as defined by the Medicaid agency, on the basis of AWP or WAC.

3. Documents Relating to Cobo Pharmacy's Costs to Purchase Drugs, Dispensing Costs, Profits, and Losses Will Demonstrate No Inflated Profits

Ven-A-Care and Cobo argue that documents concerning Cobo Pharmacy's acquisition costs, dispensing costs, profits and losses are not relevant. *See* Ven-A-Care and Cobo's Resp. at p. 7. The Court need look no further than the first paragraph of the First Amended Complaint (Master Docket No. 5614), which states "By knowingly reporting fraudulently inflated prices – sometimes 1000% higher than Dey's actual prices – Dey has

ensured that its retail customers and other providers who dispense its drugs received inflated reimbursement and profits from Medicare and Medicaid.” In order to determine whether pharmacies actually received “inflated” “profits,” Dey needs to examine the pharmacy’s costs – acquisition and dispensing – and the pharmacy’s profits and losses. Cobo Pharmacy submitted claims at issue in this lawsuit to Florida Medicaid for Dey’s albuterol, which is a subject drug in this case. Documents concerning Cobo Pharmacy’s costs, profits and/or losses relating to the dispensing of Dey’s albuterol to Medicaid patients are directly relevant to plaintiffs’ allegations in this lawsuit.

Ven-A-Care and Cobo also argue that Ven-A-Care has produced all of its pricing information and copies of all its Medicare and Medicaid claims, and thus, the same documents from Cobo Pharmacy would be duplicative. *See Ven-A-Care and Cobo’s Resp.* at p. 7. However, this argument fails. During the deposition of Ven-A-Care’s 30(b)(6) designee T. Mark Jones, Mr. Jones testified that he could not verify whether Ven-A-Care ever submitted any Medicare or Medicaid claim for Dey’s drugs:

- Q. Okay. So it would be fair to say that you’re not sure whether or not Ven-A-Care ever dispensed a Dey drug to a Medicare or a Medicaid patient?
- A. Well, I don’t want to say that we did or didn’t without the information.
- Q. Okay. I’m just going to show you a document and see if it refreshes your recollection at all. This is a document previously marked Dey Exhibit 216. Now, you’ll see that this is a claim submitted to Medicare for Albuterol Sulfate inhalation, unit dose 0.083 percent, which is a drug manufactured by Dey, but it does not say whether or not Dey manufactured this particular generic drug. Do you know whether or not this drug was manufactured by Dey that was the subject of this claim?
- A. I can’t say that I do, because there’s no indication for it.

See Katz Reply Decl., Ex. H, 12/9/08 Jones Tr., at 1081:11-1082:9.

Additionally, Ven-A-Care and Cobo make the conclusory allegation that the documents would be duplicative because Dey has received “extensive discovery related to Medicaid directly from government entities,” but have not pointed to any documents of any pharmacy from which Dey would be able to determine whether the pharmacy received “inflated profits” relating to the dispensing of Dey’s drugs to Medicaid patients. The Florida Medicaid claims referred to by Ven-A-Care and Cobo do not contain information relating to any pharmacy’s costs, profits and losses. Therefore, Ven-A-Care and Cobo have presented no evidence to support their argument based on duplication.

4. Dey Is Not Engaging in a “Fishing Expedition”

Ven-A-Care and Cobo cite cases in support of their argument that Dey is engaging in a “fishing expedition,” but all of these cases are inapposite. First, Ven-A-Care and Cobo cite to *In re Cusumano v. Microsoft Corp.*, 162 F.3d 708, 717 (1st Cir. 1998), and quote the case out of context. A more complete statement of the court’s opinion undercuts Ven-A-Care and Cobo’s argument. The court held: “It is also noteworthy that *the respondents are strangers to the antitrust litigation; insofar as the record reflects, they have no dog in that fight.*”

Although discovery is by definition invasive, parties to a law suit must accept its travails as a natural concomitant of modern civil litigation. Non-parties have a different set of expectations.” *Id.* (emphasis added). Unlike the non-party in *Cusumano*, Cobo does have a “dog” in this “fight”; indeed he is a principal of the relator and seeks to benefit financially from this litigation. Moreover, Cobo certainly had an expectation to be a participant in discovery and is not a “stranger” to this litigation as he has been involved in investigations and litigations concerning Dey for more than 13 years. *See* Point I.A., *supra*, at pp. 2-3. Indeed, Cobo is specifically identified in the First Amended Complaint as a principal officer and/or director of Relator Ven-A-Care during the relevant time period. *See* First Am. Compl. at ¶ 11.

Ven-A-Care and Cobo's reliance on the other cited cases is also misplaced. In *Blount International, Ltd. v. Schuylkill Energy Resources, Inc.*, 124 F.R.D. 523, 526 (D. Mass. 1989), the court held that the defendant could not take discovery of a third-party regarding material not relevant to the action for the purpose of discovering a right of action against that third-party which could not be brought in that action. *See id.* at 527. Here, Dey is seeking discovery directly relevant to this action and relating to its defenses against the parties in this action. In *Heidelberg Ams., Inc. v. Tokyo Kikai Seisakusho, Ltd.*, 333 F.3d 38, 39-40 (1st Cir. 2003), unlike Cobo and Ven-A-Care, the third-party did not share a principal with a party, nor was it involved in litigating against a party. Finally, Dey's motion to compel in *The State of Florida ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corp., et al.*, Case No. 98-3032A (Fla. 2d Cir. Ct.), was wrongly decided, but regardless, it is not analogous because, unlike Cobo, the principal of Andrews Drugs of Perry, Inc. was not part owner of any of the plaintiffs (Ven-A-Care or the State of Florida), and there was no evidence that the principal of Andrews Drugs of Perry, Inc. was involved in investigations or litigations concerning Dey.

II.

VEN-A-CARE IS ALSO REQUIRED TO PRODUCE THE COBO PHARMACY DOCUMENTS PURSUANT TO DEY'S DOCUMENT REQUESTS

Ven-A-Care is incorrect that Dey did not serve requests on Ven-A-Care for the Cobo Pharmacy documents at issue. As set forth in Dey's Moving Memorandum, all of the documents sought by Dey from Luis Cobo are encompassed by the Document Requests to Ven-A-Care, served on Ven-A-Care on January 18, 2008. *See* Dey Mem. at pp. 8-9; Katz Decl., Ex. P. Ven-A-Care fails to make any argument for why the Cobo Pharmacy documents are not covered by Requests 10, 27, 31, 32, 57, 58, and 59.

Instead, Ven-A-Care argues that it does not have possession, custody or control of the Cobo Pharmacy documents even though Cobo is a principal of both companies. As explained in Dey's Moving Memorandum, a party is required to produce relevant documents relating to a third-party company where those documents are within the control of the party. *See* Moving Mem. at pp. 9-10. Here, Ven-A-Care has control over the Cobo Pharmacy documents. As explained more fully in Point I.A., *supra*, at pp. 2-3, Mr. Cobo and Cobo Pharmacy are not strangers to Ven-A-Care or this litigation. Indeed, Cobo is specifically named as the principal of the relator, Ven-A-Care, in this action, and has been actively involved in investigations and litigations concerning Dey. Additionally, Cobo and Cobo Pharmacy have assisted Ven-A-Care in investigating Dey in connection with this litigation.²

CONCLUSION

For the foregoing reasons, as well as those reasons set forth in its moving memorandum of law, Dey respectfully requests that the Court compel Luis Cobo and Ven-A-Care to produce all documents concerning Cobo Pharmacy responsive to the Subpoena, as narrowed by the document requests in Dey's counsel's September 8, 2008 letter, and responsive to the Document Requests to Ven-A-Care, and grant Dey such other, further, and different relief as the Court deems to be just and proper.

Dated: January 29, 2009

Respectfully Submitted,

/s/ Clifford Katz

Paul F. Doyle (BBO # 133460)

² Ven-A-Care & Cobo also argue that "Dey believes, as the Relator does, that there will be a recovery against [Dey] in this action for fraudulent conduct." *See* Ven-A-Care and Cobo's Resp. at p. 12. This argument twists Dey's argument. It is obvious that Dey is making a hypothetical argument regarding "any recovery" in the event Dey does not prevail. *See* Moving Mem. at pp. 16-17. Dey believes it should and will prevail.

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